

K971399

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JUN 13 1997

NAME OF DEVICE: Auris AE

TYPE OF DEVICE: All-in-the-Ear

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable circuitry

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 13 battery

A USERS' MANUAL AND OTHER INFORMATION

IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris TL

TYPE OF DEVICE: All-in-the-Ear

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable circuitry

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 312 battery

A USERS' MANUAL AND OTHER INFORMATION
IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris HS

TYPE OF DEVICE: Half-shell-in-the-Canal

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable circuitry

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 312 battery

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IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris AC

TYPE OF DEVICE: All-in-the-Canal

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable
circuitry

ASSEMBLY: Assembled from standard components that
are widely used by other hearing aid
manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications
comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual
audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 312 battery

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IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris MM

TYPE OF DEVICE: Micro-Mini (All-in-the-Canal)

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable
circuitry

ASSEMBLY: Assembled from standard components that
are widely used by other hearing aid
manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications
comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by
individual audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 10A battery

A USERS' MANUAL AND OTHER INFORMATION
IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris COE

TYPE OF DEVICE: Canal-Open-Ear (All-in-the-Canal)

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable circuitry

ASSEMBLY: Assembled from standard components that are widely used by other hearing aid manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 10A battery

A USERS' MANUAL AND OTHER INFORMATION
IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I

A SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

NAME OF DEVICE: Auris CIC

TYPE OF DEVICE: Completely-in-the-Canal

INTENDED USE: To amplify and transmit sound to the ear.

FEATURES: DSD K-amp or Intrigue programmable
circuitry

ASSEMBLY: Assembled from standard components that
are widely used by other hearing aid
manufacturers.

TECHNICAL CHARACTERISTICS: "Technical specifications
comply with S3.2-1987 ANSI Standards"

FIT: Frequency response dictated by individual
audiogram

CONTROLS: Volume control similar to other devices.

POWER: Standard size 10a or 5a battery

A USERS' MANUAL AND OTHER INFORMATION
IS SUPPLIED WITH EACH HEARING AID.

ATTACHMENT I



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Roger P. Juneau
President
General Hearing Instruments, Inc.
P.O. Box 61010
New Orleans, LA 70161-1010

Re: K971399
Programmable Option for Auris AE,
Auris TL, Auris HS, Auris AC,
Auris MM, Auris COE and CIC
Air Conduction Hearing Aids
Dated: April 25, 1997
Received: April 28, 1997
Regulatory Class: I
21 CFR 874.3300/Procode: 77 ESD

Dear Mr. Juneau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

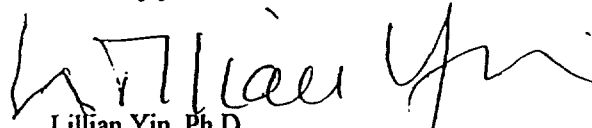
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

While your device has been deemed substantially equivalent to other legally marketed hearing aids, please be advised that electromagnetic interference from digital cellular telephones, as well as from other sources, is increasingly becoming a concern. Typically, this interference takes the form of a buzzing sound that can range from annoying to very loud and may render a hearing aid temporarily ineffective for the wearer. Because electromagnetic interference may affect your device, you may be asked to test for electromagnetic compatibility in the future. In this interim period, we encourage you to modify your device labeling to inform practitioners and users of the potential for electromagnetic interference. Please be aware that a 510(k) submission is required for any claims that infer that your device is compatible with potential sources of electromagnetic interference, such as "compatible with digital cellular telephones", and that data supporting such claims is necessary.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Lillian Yin", is written over the typed name.

Lillian Yin, Ph.D.

Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971399

Device Name: Auris AE-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to severe conductive, mixed or sensoryneural hearing loss

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Segman

Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris HS-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to severe conductive, mixed or sensoryneural hearing loss when cosmetics are of some concern

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris MM-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to moderate conductive, mixed or sensoryneural hearing loss when cosmetics are of major concern, but the ear can not accommodate a complete in the canal style

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David M. Sponson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris CIC-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to moderate conductive, mixed or sensoryneural hearing loss when cosmetics are of major concern.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Johnson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris TL-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to severe conductive, mixed or sensoryneural hearing loss when a more cosmetic AE is desired.

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ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris AC- (DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Mild to severe conductive, mixed or sensoryneural hearing loss when cosmetics are a major concern but the ear prevents use of a CIC or MM.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Sigmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971399

510(k) Number (if known): K971399

Device Name: Auris COE-(DSD K-amp) or (Intrigue-Pro) Option

Indications For Use:

Normal low and middle frequency hearing with a sloping mild to moderate high frequency sensory neural or mixed loss.

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ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Restricted Device ✓

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

David A. Gopman

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K971399